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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,061	08/03/2005	Gerold Lukowski	9015.002.US	8844

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EXAMINER	
ARIANI, KADE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
12/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,061	LUKOWSKI ET AL.	
	Examiner	Art Unit	
	Kade Ariani	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 21-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on August 17, 2009, has been received and entered.

New claims 51-54 have been added.

Claims 1-19, and 21-54 are pending in this application.

Claim Objection

The objection to claims 5 and 41 is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19, 21-50, and 51-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ strains of microalgae, macroalgae, marine fungi, cyanobacteria (*Oscillatoriales, Nostocales, Chroococcales*), and marine bacteria. It is not clear if the written description is sufficiently repeatable to avoid the need for a

deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit will be made in this application when the accession number will be assigned (see Remarks page 1 1st paragraph and amendments to the specification filed on 08/17/2009). However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code

and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-10, 16-46, and 48-50 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is withdrawn due to Applicants amendments to the claims filed on 08/17/2009.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations “biological material identified as Accession No._____" in claim 51, "a marine microorganism of Accession No. _____” in claim 52, “lipid-containing microorganisms of Accession No. _____” in claim 53, and “microorganisms of Accession No. _____” in claim 54, fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because it is no clear which biological material and/or which microorganism(s) is/are being claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19, and 21-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Müller et al. (European Journal of Pharmaceutics and Biopharamaceutics, 2000, Vol. 50, p. 161-177) in view of Medina et al. (Biotechnology Advances, 1998, Vol. 16, No. 3, p.517-580) and Olaizola M. (Journal of Applied Phycology, 2000, Vol. 12, p.499-506) and further in view of Kreitlow et al. (Journal of biotechnology, 1999, Vol. 70, p. 61-163) and Caudales et al. (International Journal of Systematic and Evolutionary Microbiology, 200,50 p.1029-1034).

Claims 1-10, 35, 38-44, 47-49, and 17-47, 28-34, 50, 51 and 54 are drawn to a composition comprising, a biomass containing a lipid component, the biomass is from of one or more marine microorganisms selected from microalgae (macroalgae, marine fungi, cyanobacteria, and marine bacteria), wherein the biomass is in a form of microparticles (or nanoparticles), and the microparticles or nanoparticles of the biomass contain a pharmaceutical (or cosmetic) activity and said activity is non-bactericidal, said nanoparticles or nanoparticles have a mean size 10 nm to 10 μm, the composition further comprising one or more additional pharmaceutically or cosmetically active substances (mineral substances, radical scavengers, dietary supplement, and vitamins), the biomass and the active substance s are heated to a temperature at or above the melting temperature of the lipid component and mixed, wherein active substances comprise Xanthones, ubiquinones with chain length of from 1 to 15, norlichexanthone, wherein the biomass is heated to a temperature at or above all the melting temperature of the liquid component, prior to homogenization, mixing with an emulsifying agent at the same temperature, the biomass is mixed with a solvent at room temperature, the

composition further comprising one or more dispersion agent, further comprising one or more dispersion-stabilizing substances, wherein the biomass comprises microalgae or macroalgae selected from the group consisting of Asparagopsis …, cyanobacteria selected from the group consisting of the class *Oscillatoriales, Nostocales, Chroococcales*, …, and marine bacteria selected from the group consisting of the genera Photobacterium,…, the microparticles or nanoparticles in a form of oils, vitamin C, one or more clay minerals are phyllosilicates, the bacteria are cultivated in the presence of clay minerals, said active substances comprise inorganic thiocyanates, and a method of using the composition of claim 1, comprising applying said composition as a pharmaceutical or cosmetic, adding said composition to a foodstuff, using the composition for gene transfer, using the composition by applying said composition to the skin or tissues, and applying said composition to skin or tissues vulnerable to *S. aureus* strains, applying said composition to skin contaminated with methicilline-resistant strains of *S. aureus*, applying said composition to skin wherein said particles further comprises xanthone derivatives.

Claims 11-15, 47, and 52 are drawn to a method for producing a pharmaceutical composition comprising, cultivating a marine microorganism selected from the group consisting of microalgae (macroalgae, marine fungi, cyanobacteria, and marine bacteria, and combinations thereof), forming a suspension of the cultivated marine microorganism that contains a lipid component, and homogenizing the suspension to from particles with a mean diameter of 10 nm -10 µm wherein the particles contain a pharmaceutical activity and said activity is non-bactericidal, homogenizing comprises

subjecting the suspension to one or more high-pressure homogenization cycles, further comprising adding one or more active substances to the suspension, spray drying, and heating the suspension to a temperature at or above the melting temperature of the lipid component prior to homogenization.

Claims 16, 30, and 53 are drawn to a method of using the biomasses of lipid containing microalgae, … as a carrier for active substances comprising adding active substances to said biomasses, wherein the active substances comprise antibiotics.

Müller et al. teach a method for producing a pharmaceutical composition (lipid nanoparticles to use in drug delivery), applying high pressure homogenization (and emulsification) to lipids to produce micro- and nanoparticles with a diameter of 10 nm to 10 μm (1000nm), heating the lipids until the liquefaction, optionally adding one or more active substances or additives, mixing the with a surfactant-water mixture heated to a temperature above the fatty acids melting points and unification of the two phases, preparation of pre-suspension, subjecting to one or more high pressure homogenization cycles, heating of the lipids and the surfactant-water mixture is omitted (cold homogenization), and active substances are adsorbed at room temperature or dispersed (p. 162, column 1, 3rd and 4th paragraphs and column 2, 1st and 2nd paragraphs, p. 163, column 1, lines 6-15, and last paragraph, p. 166, column 1, last 3 lines), subsequent spray drying or lyophilization (p. 171, column 2, part 9., lines 6-14), formation of an emulsion of water and lipids, dissolving the emulsion in an appropriate organic solvent, (p. 164, column 1, 2nd paragraph, lines 4-8). Müller et al. also teach a composition comprising lipid nanoparticles (SNL) with a diameter of 10 nm to 10 μm (p.

162, column 2, line 2), and the use of lipid nanoparticles as a carrier for drug delivery, vitamin, ubiquinones (Coenzyme Q10), radical scavenger, dietary supplements (p.164, Table 1.). Müller et al. also teach using the nanoparticles for topical drug delivery, and control release from SLN incorporated into creams (p. 171 1st column 1st and 3rd paragraph, and 2nd column 1st paragraph). Müller et al. also teach that lipids from food industry can be used in solid lipid nanoparticles (SLN). Müller et al. further teach the lipid used as matrix promotes drug solubilization has mono- and diglycerides, and the chemical nature of the lipid is important. More complex lipids being mixtures of mono-, di- and triglycerides and also containing fatty acids of different chain length offering space to accommodate the drugs. Chemically polydisperse lipids such as those used in cosmetics showed very good drug incorporation capacities (p.164 column 1, last 2 paragraphs, column 2, lines 1-9, and p.165 column 1, lines 1-2).

Müller et al. do not teach cultivating a marine microorganism in the presence of clay minerals, microalgae, and homogenizing a suspension of the cultivated marine microorganism, cyanobacteria, *Oscillatoriales, Chroococcales,* and *Nostocales*. However, Medina et al. teach a process of cultivating microalgae (p.524 1st paragraph lines line 2), pretreatment by forming a suspension and homogenizing cells (cell disrupting methods) (p.526 3rd and 4th paragraphs), drying and lyophilization of biomass (p.527 2nd paragraph). Moreover, Olaizola teach a process comprising cultivating marine microalgae and subjecting the biomass to high pressure homogenization (Abstract, and p.501 2nd column 3rd paragraph).

Furthermore, Kreitlow et al. teach cyanobacteria (*Oscillatoriales, Chroococcales,* and *Nostocales)*. Kreitlow et al. teach the inhibition of the growth of *S. aureus* by hydrophilic extracts obtained from cyanobacterial strains (p. 62 1st column 2nd paragraph, and 2nd column 2nd paragraph, lines 15-17).

Further motivation to use microalgae biomass as a source of lipid to produce nanoparticles is in Caudales et al. who teach the presence of high proportions of saturated straight chain and unsaturated straight chain fatty acids, mono- and poly-unsaturated fatty acids, and also fatty acids of different chain length in different strains of cyanobacteria (*Oscillatoriales, Chroococcales,* and *Nostocales*) (p.1032 1st column 1st and 2nd paragraphs, 2nd column 1st paragraph, and Table 2. columns 2-4).

Moreover, at the time the invention was made, phyllosilicates and fibrous clay were among the most widely used minerals in the composition of medicines and were being used as pharmaceutical excipients. Also, at the time the invention was made the anti-inflammatory properties of xanthone derivative (alpha-mangostin) and the antifungal and antibacterial properties of thiocayanate, were well known in the art.

Therefore, a person of ordinary skill in the art at the time the invention was made could have been motivated to combine the prior art teachings by subjecting the lipid containing biomass as taught by Media et al. to the method as taught by Müller et al. according to the teachings of Olaizola with predictable results of providing a method for producing a pharmaceutical composition and a composition comprising the lipid containing biomass in the form of nanoparticles. The motivation to use a marine microorganism biomass in the method of Müller et al. would be the presence of a

mixture of mono-, di- and triglycerides and fatty acids (of different chain lengths) and bioactive compounds in its biomass. Moreover, a person of ordinary skill in the art at the time the invention was made could have been motivated to use the composition comprising the lipid containing biomass in the form of nanoparticles (as a carrier) by mixing the composition with cosmetics (or pharmaceutical, and foodstuff), and by applying the composition to skin according to the teachings of Müller et al. with a reasonable expectation of success to provide a carrier for an active substance. The motivation would be to use the composition for drug delivery. Accordingly, a person of ordinary skill in the art at the time the invention was made, could have been motivated to additionally use a xanthone derivative and/or thiocayanate in the method as taught by Müller et al. reasonable expectation of success to provide a composition with antibacterial, and anti-inflammatory properties. The motivation would be their antifungal and antibacterial, and anti-inflammatory properties.

Answer to the arguments

Applicant's arguments filed on 08/17/2009 have been fully considered but they are not persuasive.

With respect to the rejection of claims 1-19, 21-50, and 50 under 35 U.S.C. 112, first paragraph, Applicant argues (p.15 of 2nd paragraph lines 6-8 Remarks filed on 08/17/2009) that the microorganisms disclosed are believed to be generally available to the public and then Applicant argues (Remarks p.15 3rd paragraph lines 1-5) that the

biological material identified in the specification as Bio 30 has been deposited. These arguments are contradictory and are not found persuasive because it is not clear which claimed microorganism is generally available and which microorganism is not, and the biological material identified in the specification as Bio 30, is not in the rejected claims. Therefore, the rejection is maintained.

With respect to the rejection of claims 1-19, 21-50 under 35 U.S.C. 103(a), Applicant argues that Muller is directed to the manufacture and use of highly purified lipids and Applicant's claimed invention is directed to a biomass of marine microorganisms. These arguments are not found persuasive, because the claims do not necessarily require the marine microorganism(s) to be included in the composition.

Applicant argues that Example 6 and 8-11, and Example 2 and Figure 1. in the disclosure shows that a synergistic effect exist when the biomass of the claimed invention is coupled with known pharmaceutically active substances. These arguments are no found persuasive because Example 1, and 8-11 disclose production of micro- and nanoparticles from the biomass of various marine microorganism, also Figure 1. compares the result of the effect of micro- and nanoparticles from strain B30 algal biomass in comparison to a formulation of B30, and the components of the formulation is not clear, and there is no result to show the synergistic effect of a composition comprising the biomass containing the lipid component obtained from all the claimed microalgae, macroalgae, marine fungi, cyanobacteria and marine bacteria with known pharmaceutically active substances. Moreover, a greater than additive effect is not necessarily sufficient to overcome a prima facie case of obviousness because such an

effect can either be expected or unexpected, and as mentioned immediately above, Kreitlow et al. teach the inhibition of the growth of *S. aureus* by hydrophilic extracts obtained from cyanobacterial strains, therefore a person of ordinary skill in the art would have expect to observe an inhibitory activity against the pathogen.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651